



DOCKET NO.: CEPH-2313/CP188-C

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Sankar Chatterjee, et al.

Application No.: 10/685,923

Filing Date: October 14, 2003

For: PEPTIDE-CONTAINING ALPHA-KETOAMIDE CYSTEINE AND SERINE  
PROTEASE INHIBITORS

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT:

*November 19, 2003*

I HEREBY CERTIFY THAT THIS PAPER IS BEING  
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*Elizabeth A. McLoud*

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

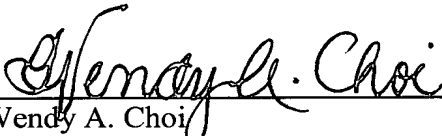
- ☒ In view of the voluminous nature of references **4 and 10**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - ☒ Copies of references **1-11, 16-32 and 39** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/166,808 now U.S. Patent No. 6,150,378**, filed **October 6, 1998**; copies of references **12-15 and 33** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/527,540 now U.S. Patent 6,288,231**, filed **March 16, 2002**; copies of references **34-36 and 40** listed on the attached Form

PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. 09/879,336, filed June 12, 2001.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: November 19, 2003

  
Wendy A. Choi  
Registration No. 36,697

WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. CEPH-2313/CP188-C	Application No. 10/685,923
		Applicant Sankar Chatterjee, et al.	
		Filing Date October 14, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	1	Amparo, E. C. et al., "Preparation of .alpha.-aminoboronic acid and ester as inhibitors of thrombin", Chemical Abstract, <b>1996</b> , Vol. 125(17), page 1172, Abstract No. 222432	
	2	Amparo, E.C. et al., "Boronic acid and ester inhibitors of thrombin", Chemical Abstract, <b>1997</b> , Vol. 126(3), page 594, Abstract No. 31466	
	3	Bihovsky et al., "Preparation of benzothiazine- and related heterocyclic group-containing amino acids as cysteine and serine protease inhibitors", Chemical Abstract, <b>1998</b> , Vol. 129, WO 98/21186, Abstract No. 28214	
*	4	Green, T.W., et al., Protective Groups in Organic Synthesis, 2 <sup>nd</sup> Ed., Wiley & Sons, <b>1991</b>	
	5	Harbeson, S.L., et al., "Stereospecific synthesis of peptidyl $\beta$ -keto amides as inhibitors of calpain," <i>J. Med. Chem.</i> , <b>1994</b> , 37, 2918-2929	
	6	Lehninger, <i>Biochemistry</i> , 2 <sup>nd</sup> Ed., Worth Publishers, Inc., <b>1975</b> , 73-75	
	7	Meyer, S.L., et al., "Biologically active monomeric and heterodimeric recombinant human calpain I produced using the baculovirus expression system," <i>Biochem. J.</i> , <b>1996</b> , 314, 511-519	
	8	Nagase, H. et al., "Preparation of morphinan derivatives as analgesics and diuretics", Chemical Abstract, <b>1994</b> , Vol. 120(13), page 1236, Abstract No. 164625	
	9	Tsushima, T. et al., "Preparation of amino acid derivatives as digestive tract hormone antagonists", Chemical Abstract, <b>1992</b> , Vol. 116(25), page 838, Abstract No. 256040	
*	10	Remington's Pharmaceutical Sciences, Mack Publishing Company, Easton, PA, <b>1980</b>	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



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	Confirmation No. Not Yet Assigned			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>				
	11	Winterbottom, et al., "Studies in chemotherapy, XV. Amides of pantoyltaurine," <i>J. Am. Chem. Soc.</i> , <b>1947</b> , 69, 1393-1401		
	12	Bihovsky, R., et al., <i>USpatful</i> , <b>1999</b> , 110318		
	13	Bihovsky, R., et al., <i>Caplus</i> , <b>1998</b> , 129, 28214		
	14	Chatterjee, S., et al., <i>Caplus</i> , <b>1999</b> , 131, 337341		
	15	Chatterjee, S., et al., <i>Caplus</i> , <b>1999</b> , 131, 306757		
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### U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	16	5,034,376	07/1991	Hoover, et al.	514	18
	17	5,162,500	11/1992	Takeuchi, et al.	530	330
	18	5,340,825	08/1994	Horwell, et al.	514	339
	19	5,444,042	08/1995	Bartus, et al.	514	2
	20	5,514,694	05/1996	Powers, et al.	514	357
	21	5,563,127	10/1996	Amparo, et al.	514	64
	22	5,610,297	03/1997	Powers	544	168
	23	5,614,649	03/1997	Iqbal, et al.	554	56
	24	5,646,121	07/1997	Häbich, et al.	514	18
	25	5,650,508	07/1997	Powers	544	168

### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	26	0 604 183 A1	06/29/94	EP		
	27	WO 95/00535	01/1995	PCT		
	28	WO 96/14857	05/1996	PCT		
	29	WO 96/20689	07/1996	PCT		
	30	WO 96/39385	12/1996	PCT		

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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	31	5,658,885	08/1997	Lee, et al.	514	19
	32	5,698,538	12/1997	Amparo, et al.	514	64
	33	5,763,576	06/1998	Powers	530	330
	34	5,952,328	09/1999	Bihovsky, et al.	514	223.2
	35	6,083,944	07/2000	Chatterjee, et al.	514	235.2
	36	6,310,057	10/2001	Chatterjee, et al.	514	212.08
	37	6,150,378	11/21/00	Chatterjee, et al.	514	336
	38	6,288,231 B1	09/11/01	Chatterjee, et al.	544	316

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	39	WO 98/25883	06/1998	PCT		
	40	WO 96/16070	05/1998	PCT		

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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